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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,876	12/12/2001	Eileen White	RUT 98-0058	5628

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EXAMINER	
YU, MISOOK	
ART UNIT	**PAPER NUMBER**
1642	16

DATE MAILED: 05/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/674,876	WHITE ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) *4-8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

This application contains claims 4-8 drawn to an invention nonelected with traverse in Paper No. 12. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 4-8 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1-8 are pending and claims 1-3 are examined on merits.

Claim Rejections - 35 USC § 112

Claims 1-3 remain rejected for reciting "recombinant cell" under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant argument is not consistent for what is the metes and bounds of "recombinant cell". Applicant appears to argue the limitation "recombinant cell" is defined in Merriam-Webster's Collegiate Dictionary as cell "containing recombinant DNA" and then applicant goes on saying that recombinant cell means stably transfected cell. According to Merriam-Webster's Collegiate Dictionary, recombinant cell is any cell containing recombinant DNA whether it is transiently transfected or stably transfected and it is not limited to stably transfected recombinant cell line as applicant appears to argue at page 3 line 6 from bottom.

Rejection of claims 1-3, for all other reasons, under 35 U.S.C. 112, second paragraph is withdrawn because of either the amendment or persuasive applicant's argument.

Claim Rejections - 35 USC § 103

Claims 1-3 remain rejected for reason of record under 35 U.S.C. 103(a) as being unpatentable over Lill et al (June 19, 1997, Nature Vol. 387, pages 823-27), Gu et al

(June 19, 1997, Nature Vol. 387, pages 819-823), or Arany et al (a copy provided with the search report, November 1997, Proc. Natl. Acad. Sci. USA, vol. 93, pages 12969-12973), and further in view of US Pat 5,607,967 and Gurtu et al (1996, Biochemical and Biophysical Research Communications Vol. 229, pages 295-298).

Applicant argues that the recombinant cells of the primary references are transiently transfected, therefore not an obvious reference and the primary references teach only one reporter gene. These arguments are not persuasive in light of applicant's argument (see rejection under 35 U.S.C. 112, second paragraph above) that "recombinant cell" is defined according to Merriam-Webster's Collegiate Dictionary definition, therefore whether the cells are transiently transfected or not is irrelevant issue because cells containing a recombinant DNA are recombinant cells. The Office now interprets recombinant cell as any cell containing recombinant DNA no matter whether the recombinant cell is transiently expressed or stably expressed. The primary references teach at least two different reporter genes. See especially Lill et al, where CAT and Luc is described as reporter gene. Applicant further argues that the cited references do not teach and/or give motivation to use control plasmid , i.e., a non p300/CBP response promoter linked to a second reporter gene in the recombinant cell but this argument is not persuasive because Lill et al teach a control plasmid, which is not activated by p300, i.e., MG_{15}-CAT (a control plasmid that does not respond to p53 no matter how much p300/CBP is added) and also teach a control is necessary in any scientific experiment to confirm a positive data, in the case of Lill et al, to confirm the reporter gene transcription occurred through p300/CBP-mediated p53 coactivation. Note page 823 right column and Figure 2.

Applicant further argues that Arany et al only teach p300/CBP-HIF complex as a possible targets but do not teach p300 is a possible target for regulation of apoptosis or suggest that p300 could be a possible target in the absence of HIF. This argument is not persuasive either because all of the three primary references teach that p300 does not act alone on p300 response promoter (it appears the art uses "p53 responsive promoter" instead of "p300 response promoter", seeFig. 2e of Lill et al at page 825) but p300/CBP proteins act as transcriptional coactivators, forming complex with other

proteins in order to act as transcription regulator. This indicates p300/CBP alone does not have any in vivo biological significance, therefore applicant's argument that the art does not provide motivation to screen useful compounds that target p300/CBP is not convincing. The three primary references teach that transcription activation (transactivation) involves multiple proteins complex. The main point of Arany et al is determination of involvement of p300/CBP in transactivation of important genes for tumor development (see the line of the abstract), thus suggesting p300/CBP might be important target for regulation of tumor development. Further Gu et al and Lill et al teach p300/CBP coactivator involvement in p53 (tumor suppressor) mediated transactivation; this also suggest that p300/CBP is a target for intervention of tumor development because p300/CBP is form complex with p53 in order for transactivation activity. The art teaches that p53 is a important gene that involved in tumor dev All three primary references suggest that p300/CBP might be a target for intervention of tumor development because p300/CBP forms complex with p53 implicated in many different tumors. US Pat 5,607,967 is cited to show that current state of art using transactivation of reporter gene as a simple way of screening useful compounds when the in vivo target acts as transcription regulator. Gurtu et al is cited to show that current state of art that making recombinant cell using selective marker is well known technique in the art before the effective filing date of the instant application. The prior art teach all the claimed limitation and provides motivation why one in ordinary skill in the art would be motivated to screen useful compounds that enhance p300/CBP activity, in turn enhances wild type p53 tumor suppressor protein activity to control tumor development or treat cancer. Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to practice the invention with reasonable expectation of success.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu
April 29, 2003

MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800
1600